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Docket No. JAB1525

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Peter Frank Ekhart  
Serial No. : 10/069,673 Art Unit: 1617  
Filed : October 15, 2002 Examiner: Jennifer M. Kim  
For : VETERINARY FORMULATION FOR ADMINISTRATION OF A  
WATER-INSOLUBLE DRUG TO A TARGET ANIMAL THROUGH A  
WATER DISTRIBUTION SYSTEM

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January 16, 2006

(Date)

Ellen Ciambrone Coletti

Name of applicant, assignee, or Registered Representative

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(Signature)

January 16, 2006

(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE**

Dear Sir:

This is in response to the office communication mailed December 28, 2005 in the captioned application. The communication stated that the S-signature in the reply sent on October 18, 2005 was improper because the underline was improperly placed before the S-signature and because the name of representative was not stated under the S-signature. A reply with proper S-signature is incorporated herein.

The claims pending and under consideration are claims 1-10.

Claims 5-8 are objected to under 37 CFR 1.75(c) as allegedly in improper form because "a multiple dependent claim cannot depend from any other multiple dependent claim". This rejection is respectfully traversed.

Applicants note that claims 5-8 were amended by Preliminary Amendment dated February 2, 2002 to each depend from claim 1.

Claims 1-10 are rejected under 35 USC 103(a) as allegedly unpatentable over Lur'e et al.<sup>1</sup> (Meditsinskaya Parazitologiya I Parazitarnye Bolezni (1987) abstract) in view of Dick et al (FR 2336931) of record. This rejection is respectfully traversed.

In the Office Action, it is asserted that:

[i]t would have been obvious to one of ordinary skill in the art to formulate the formulation comprising mebendazole and sunflower oil with optimizing ratios in any formulation. One would have been motivated to make such a modification since the formulation taught by Lur'e et al. prolonged the maintenance of therapeutic levels of active compound (mebendazole) in mice experimentation as taught by Lure'e et al. and because benzimidazole compounds (e.g. mebendazole) are well-known to be combined with water to formulate a suspension as taught by Dick et al.

Initially, applicants note that the claimed invention is directed to a method of preparing a veterinary composition comprising a water-insoluble active compound suitable for administering to a target animal through a water distribution system, comprising mixing the active compound with a water-immiscible liquid in such a manner that the mixture of active compound and water-immiscible liquid has a density between 0.85 and 1.2, and suspending said mixture in an aqueous carrier.

Applicants submit that Lur'e et al. describe formulations of mebendazole in a vegetable oil (see page 2 of the translation – materials and methods). These oily formulations of mebendazole do not comprise water.

Lur'e et al. is directed to enhancing the bioavailability of mebendazole. The solution to this problem was the formulation of mebendazole in a vegetable oil. Lur'e et al. does not teach or suggest aqueous suspensions of mebendazole with vegetable oils.

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<sup>1</sup> An English language translation of Lur'e is submitted herewith and listed on accompanying Form 1449.

FR2336931 teaches a wide variety of compositions comprising benzimidazole anthelmintics including aqueous suspensions comprising mebendazole. FR2336931 does not teach or suggest the use of vegetable oils in aqueous suspensions.

The present invention sets out to solve the problem of administration of water insoluble active compound through the drinking water systems presently used in animal keeping and/or production facilities.

This problem is solved in the present invention by a suspo-emulsion obtained by mixing the water insoluble active compound, a water-immiscible liquid and water in such a manner that the mixture of active compound and water immiscible liquid has a density between 0.85 and 1.2.

Hence the problem solved by the present invention, i.e. administration of water insoluble active compounds through a drinking water system, is a totally different problem than the one solved by Lur'e et al. i.e. improving bio-availability. Since Lur'e et al. does not teach how to administer water insoluble active compounds through a drinking water system, there would have been no motivation for the skilled person to apply the teaching of Lur'e et al. to FR2336931.

Based on the foregoing, applicants submit that no one of either Lur'e or FR2336931, alone or taken together, teach or suggest the claimed invention.

Accordingly, applicants request that the rejection under 35 USC §103(a) be withdrawn.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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Dated: January 16, 2006